MAR 1 7 2003

K024183

XII. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS. May 30, 1997. [Separate Pages]

I.* Submitter: Greg Wiita, Alton LLC., 2655 North Ocean Dr., Suite 430, Singer Island FL 33404, Phone: 561-721-9595

II. Classification Names and numbers: Acc. to Ultrasound Probe, Stepping Device, Code ITX

III. Common/Usual Name: Stepping and Stabilization Device

IV. Proprietary Names: Alton™ PT Stepper and Stabilizing System

V. Establishment Registration Number: in process

VI. Classification: Acc. to ultrasonic transducer, Class II, CFR 892.1570

VII. Substantial Equivalence: Alton™ is substantially equivalent to the classified device and those cleared for marketing by the 510(k) process under K-972152 (DevMed), K-011581) (Amertek), K-864807 (Teknar), K-871413 (Civco), K-913293 (Mick Radio-Nuc.) and K-963302 (Tayman Medical) as well as K-972672 and K000960 by Barzell-Whitmeore

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use, as the equivalent devices the classified device and those cleared for marketing by the 510(k) process under K802032 and K913293 (Mick Radio-Nuclear), under K864807 (Teknar Corp.) and others listed above.

2. The technological characteristics for this product are the same as those for the predicate devices and those currently on the market.

3. Descriptive information provided shows that the materials from which Alton™ is made are substantially equivalent to (nearly identical with some) those of similar products, used for identical purposes, currently on the market.

4. The FDA "Decision-Making Process" chart was used and appears in Attachment IV.

K024183

We believe we have complied fully with guidance documents and usual practices in preparing premarket notifications. If additional information or explanation is needed, please call me at 561-721-0595 or fax me at 561-842-6660. You may also call or fax Dr. Neal Dunning at 301-229-2138. Your prompt consideration will be appreciated.

Sincerely yours,

Greg Wiita
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2003

Mr. Greg Wiita
President
Alton Design, LLC
2655 N. Ocean Drive, Suite 403
SINGER ISLAND FL 33404

Re: K024183
Trade/Device Name: ALTON™ PT Stepper
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 KXK and ITX
Dated: November 20, 2002
Received: December 19, 2002

Dear Mr. Wiita:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

VIII.1 Indications for Use: [Separate Page]

510(k) Number: NA K024183

Device Name: Alton™ PT

The Alton PT Stabilizer and Stepper is designed to allow precision ultrasound probe alignment, precise prostate visualization and radioactive seed implantation in brachytherapy treatments. A specific application is the treatment of prostate (or other) cancer.
It is also used to allow precision ultrasound alignment and precise prostate visualization in cryotherapy treatments for prostate treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K024183